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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/664,186	09/18/2000	Jay Wayne	NEB-135-C	3837

28986 7590 11/23/2001  
NEW ENGLAND BIOLABS, INC.  
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EXAMINER
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SANDALS, WILLIAM O

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 11/23/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 09/664,186 Applicant(s) Wayne et al.  
Examiner William Sandals Art Unit 1636



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Sep 18, 2000

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-10 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) \_\_\_\_\_ is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims 1-10 are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

15)  Notice of References Cited (PTO-892) 18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-3, drawn to an isolated DNA comprising SEQ ID NO:4, classified in class 536, subclass 23.1.
  - II. Claim 4, drawn to an E. coli transformed with the plasmid of claim 2, classified in class 435, subclass 488.
  - III. Claim 5, drawn to a *Thermus* spp. transformed with the plasmid of claim 2, classified in class 435, subclass 476.
  - IV. Claims 3 and 6, drawn to an isolated DNA encoding a *Thermus* spp. promoter, SEQ ID NO:5, classified in class 536, subclass 24.1.
  - V. Claim 7, drawn to an isolated DNA encoding a *Thermus* spp. replication protein, SEQ ID NO:7, classified in class 536, subclass 23.7.
  - VI. Claims 7 and 8, drawn to a recombinant plasmid comprising a functional origin of replication comprising SEQ ID NO:s 1-3 and 9-15 and also comprising SEQ ID NO:7, classified in class 536, subclass 24.1.
  - VII. Claim 9, drawn to an E. coli transformed with the plasmid of claim 8, classified in class 435, subclass 488.

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VIII. Claim 10, drawn to a *Thermus* spp. transformed with the plasmid of claim 8, classified in class 435, subclass 476.

2. Claim 3 of the invention of Group I will be examined only insofar as the combination of claimed elements is present with the isolated DNA sequence of SEQ ID NO:1.
3. Claim 3 of the invention of Group IV will be examined only insofar as the combination of claimed elements is present with the promoter sequence of SEQ ID NO:5.
4. Claim 7 of the invention of Group VI will be examined only insofar as the combination of claimed elements is present with the functional origin of replication comprising SEQ ID NO:s 1-3 and 9-15.
5. The inventions are distinct, each from the other because of the following reasons:
  6. Inventions of Group I and Groups II and III are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as a probe or primer and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be

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obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. The protein of Group I and the nucleic acid of Groups IV, V and VI are chemically, biologically and functionally distinct from each other and thus one does not render the other obvious. The protein of Group I is not required to produce the DNA of Groups IV, V and VI (the DNA can be replicated in vectors without the use of the protein) and the DNA of Groups IV, V and VI is not required to produce the protein of Group I (which can be produced synthetically or isolated from cells). Therefore, the inventions of the two groups are capable of supporting separate patents.

8. Inventions of Groups IV, V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are chemically, biologically and functionally distinct molecules which are capable of supporting separate inventions of Group VI and Groups VII and VIII are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as a probe or primer and the inventions are deemed patentably distinct since

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there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications, and because each of Groups I-VIII are distinct and different compositions the inventions would require non-coextensive literature searches. Therefore, restriction for examination purposes as indicated is proper.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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***Conclusion***

12. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Friday from 8:30 AM to 5:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Schwartzman can be reached at (703) 308-7307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Zeta Adams, whose telephone number is (703) 305-3291.

William Sandals, Ph.D.  
Examiner  
October 25, 2001



TERRY MCKELVEY  
PRIMARY EXAMINER